DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 6 1996

WARNING LETTER
VIA FEDERAL EXPRESS

Mr. Guido J.M. Houg
General Manager
Dyna Dental Engineering B.V.
Korenbeursstraat 26
Postbus 70
4600 AB Bergen op Zoom
The Netherlands

Dear Mr. Houg:

During an inspection of your manufacturing facility located at Korenbeursstraat 26, Postbus 70, 4600 AB Bergen op Zoom, from September 9 through 12, 1996, our investigator determined that your firm manufactures sterile dental implants and non-sterile memory abutments. These products are devices as defined by the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that this device is adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820 as follows:

1. Failure to establish and implement specification control measures to assure that the design basis for the device and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example:

a.)Packaging integrity after sterilization is not validated.

Response: The firm's October 3 response promised correction by 12/96. They added that they will obtain information about the outer packaging materials (peel pouch) from the supplier of the material.

b.)The sterilization process is not validated. The Certificate of Analysis and dosimetry test data supplied by the sterilization contractor is relied on to determine that the products have been sterilized. Dyna Dental does not supply the sterilization company with specifications on how the sterilization is to be done. However, Dyna Dental is aware that a dose of [redacted] of gamma radiation is used by the contract sterilizer.

2. Failure of the device master record to include indication of authorization for any changes by the signature of a designated individual, as required by 21 CFR 820.181(a). For example, the device master record is not under formal change control or signed and dated by a designated individual.

3. Failure of the device master record to include device specifications, production process specifications, quality assurance procedures and specifications, packaging and labeling specifications, as required by 21 CFR 820.181(b). For example, the device master record does not include a description of QC procedures and specifications.

Your October 3 response to observations 2 and 3 promised correction by 10/96.

4. Failure to check finished devices and, where necessary, test for conformance with device specifications to assure that device specifications are met, as required by 21 CFR 820.160. For example, no final inspection is done on the memory abutments, ie., after polishing/blasting steps.

You advised our investigator that the person preforming this procedure will make a record of the inspection starting immediately.

5. Failure to perform planned and periodic audits in accordance with written procedures by appropriately trained individuals not having direct responsibility for the matters being audited, as required by 21 CFR 820.20(b). For example, internal audits of the quality assurance program are not performed.

You advised the FDA investigator that an internal audit will be completed by October 1996, and that internal audits will be performed yearly at a minimum.

6. Failure to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications, as required by 21 CFR 820.198(b). For example, a complaint system is in place, however failure investigation and follow-up is not documented. The system only shows that a requisition for replacement product is entered.

You advised our investigator that your firm will immediately begin formally documenting failure investigations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Therefore, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information in to account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Your October 3 response letter indicates that your firm will have completely addressed the deficiencies listed above by December 1996. Please notify this office when you have implemented the corrections of these deficiencies.

Your response should be sent to the attention of Mr. Sterling D. Gary, Dental, ENT and Ophthalmic Devices Branch, at the above Gaither Road address.

Sincerely,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological Health